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February 16, 1994

VIA FACSIMILE AND FIRST CLASS MAIL

Mr. Brian J. Malkin
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
FOOD AND DRUG ADMINISTRATION
5600 Fisher's Lane, Room 15-22
Rockville, Maryland 20857

Re: Reality Female Condom
Patent Term Extension
U.S. Patent No. 4,735,621
FDA Docket No. 93E-0290

Dear Mr. Malkin:

Chartex International Plc provides the following information in response to your inquiry regarding the early U.K. studies of the Reality/Femidom brand female condom.

The original U.K. clinical studies occurred at the following times.

Acceptability Study -	Started	October 1987
	Finished	May 1988
Efficacy Study -	Started	February 1989
	Finished	June 1990

Neither an IDE nor IRB approval was required for these studies. The date on which the device was first used with human subjects as part of a clinical investigation to be filed with the FDA to secure pre-market approval of the device was in October, 1987. Therefore, the applicant identifies October 31, 1987, as the most certain date upon which such a study occurred.

If additional information is required, please do not hesitate to contact us.

Sincerely yours,

Paul Grandinetti

PG:jt
cc: Ms. Joan Hann